Title:	**Quality Control Record Sheet**	Document:	**wi/qcrs/0.14a**
	RBA AChRAb Assay QC data	Revision:	**7**
Prepared by: Geoff Flood		Date:	**6 Sep 2018**
Approved by: Rachael Price		Page	**1 of 2**

Kit lot no:	**KRBA309**	Expiry date:	**14 Jun 2021**
Labelled Receptor lot no:	**RBA309**	Expiry date:	14 Jun 2021
Reconstitution buffer lot no:	**161B**	Expiry date:	26 Aug 2021
Precipitation enhancer lot no:	**PE177A**	Expiry date:	27 Jan 2022
Anti human IgG lot no:	**179Gf**	Expiry date:	18 Jan 2022
Normal Human serum lot no:	**DLA111y**	Expiry date:	18 Jan 2022
Washing solution lot no:	**402W**	Expiry date:	23 Jan 2022
Negative control lot no:	**124Np**	Expiry date:	18 Jan 2022
Positive control lot no:	**114PCaf**	Expiry date:	18 Jan 2022

Total cpm in 50μL of labelled receptor: _____75445_____

Serum sample (5 μL)	cpm bound	nmole/litre toxin bound
Negative control	1254	-
Positive control (range)	8369	5.3 (3.3 – 6.7)
QC sera (neat and diluted in normal human serum)		
(A) K3 (lot_____B)	4503	2.4
K3/2	3127	1.4
(B) K4 (lot_____E_____)	1891	0.48
K4/2	1715	0.35
(C) K5 (lot_____C_____)	11341	7.6
K5/2	7448	4.7
ε-specific serum	7922	5.0
MG7a	15644	10.8
MG6b	12501	8.4

Specific activity of toxin (K):_____166_____ Ci/mmol % Counter Efficiency:_____72.3%_____

Receptor labelling date: _____12 Apr 2021_____ Receptor expiry date:_____14 Jun 2021_____

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Assay date (weeks after receptor labelling)	Decay factor (A)
Up to 1 week	1.0
+ 1 – 2 weeks	1.1
+ 2 – 3 weeks	1.2
+ 3 – 4 weeks	1.3
+ 4 – 5 weeks	1.4
+ 5 – 6 weeks	1.5
+ 6 – 7 weeks	1.6
+ 7 – 8 weeks	1.75
+ 8 – 9 weeks	1.9

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay date:	**15 Apr 2021**	Authorised by:	DR G Flood
Performed by:	pp **A Lee**	Signature:	
Signature:	*Bradbury*	Position:	**Head of Quality Control**
Position:	**Principal Technician**	Date:	16TH APR 2021